Bra on Amiflopyrine and Its derivatives

621. SHBI BAFIQUE ALAM: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Amidopyrine has been withdrawn for marketing- in India but its derivatives are being promoted for human consumption;

(b) if so, names of its derivatives being allowed for marketing in t&e country;

(c) whether it is a fact that Mey-lers 198&, WHO Drug Information 197', Manimili 1979, y Martindale 19&2 and American Medical Association Drug Evaluations 1973 have warned the dangerous and fatal effects of these-derivatives;

(d) whether it is a fact that these derivatives are being marketed in India with tranquillisers;

(e) if so, the names of these formulations;

(f) whether it is also a fact that such combinations result severe low body temperature; and

(g) if so, what is the justification of allowing these derivatives and combinations for human consumption?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SA-RjDj KHAPARDE): (a) Yes, Sir.

(b) Analgin, a methanesulfonate derivative of Amidopyrine and some other derivatives of Amidopyrine are available in combination with other drugs.

(c) Agranulocytosis, a blodd disorder is reported to be a rare adverse reac tion in mmimai sensitive population of a number of analgesic/anti-inflam matory drugs including analgin.

(d) and (e) Statement annexed *(See* below)

(f) The drug is reported to be an excellent temperature lowering pain-killing and anti-inflammatory agent. As a result of its first property, if dose is exceeded, it may result In severe low body temperature.

(g) Bostons Epidemiological study, published recently have shown that the risk of agranulocytosis due to Analgin is very insignificant. As per the information available the benefit of the drug outweighs its risks, so as to justify its continued marketing.

Statement

Combinations of-Analgin with Tranquillisers marketed in the Country

S. No. Name of the Product	Composition	Marketed By
1. Codolsic Tablets.	... Analgin Bromide Diazepam	M/s. FDC, Bombay Clidinium
2. Famagin Tablets...	Analgin Diazepam	M/s. Alfcem,, Bombay
	Dia-zepam Diphenhydramine	M's. M. M. Labs., Bombay.

Licences without Verification

622. SHRI RAFIQUE ALAM: Will he Minister of HEALTH AND FAMILY WELFARE be pleased to refer to the answer to Starred Question J94 given in the Rajya Sabha on the IBth March, 1987 and state:

(a) whether it is a fact that fresi manufacturing licences as well I renewal of licences have been gran ted without verifying quality contro

and testing laboratories as require under the Drugs and Cosmetic Rulei by Drug Authorites;

(b) if so, the number of units in operation without quality control and testing laboratories;

(c) what are the reasons for allowing manufacture of medicines without testing laboratories;

(d) whether it is a fact that joint inspections consisting of State and Central Authorities are also being done in most of cases;

(e) if so, the details of such inspections done during the last three years, years-wise along with the findings in each case; and

(f) what are the names of the companies whose manufacturing licences have not been revalidated due to non-compliance of mandatory requirements during the last three years, year-wise along with details in each case? -

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (c) It is noT a *tSct* that fresh manufacturing licences as well as renewal of licences have been granted without verifying quality control and testing laboratories as required under the Drugs and Cosmetics Rules by Drugs Authorities. As per Drugs and Cosmetics Rules all Drugs Manufacturers are required to have their own testing laboratories. Available information with the Government reveals that there are about 393 units without testing laboratories. Recently sojne of the units have obtained stay orders in Bombay High Court against the order of the Commissioner Food and Drugs Administration, Maharashtra State asking them to provide Analytical Laboratories.

(d) Yes, Sir.

(e) The Zonal Officer of the Central Drugs Standard Control Organisation conduct joint/independent inspections in States coming under their respective Zones whenever required Details of the inspections carried out during the last three years, year-wise is given below;

Year	1983-84	1984-85	1985-86
No. of Joint Independent Inspection carried out	lo51	1052	1183

(f) Information is being collected and will be laid on the Table of the Sabha.

Commission vendors at railway stations

623. SHRI SHAMIM AHMED SIDDI; Will the Minister of RAILWAYS be pleased to state-

(a) what is the total number of commission vendors engaged under Departmental Catering/Vending units at Delhi, Allahabad, Kanpur, Tundla and Moradabad stations under the Northern Railway;

(D) what is the rate of commission paid to such vendors engaged in Catering and Vending Units, separately together "with the date of fixation of their rates;

(c) the profits earned by RaiL ways at above stations during the period 1983 to 1986, year-wise, separately; and

(d) what are the reasons for not increasing their commission?

THE MINISTER OF STATE OF THE MINISTRY OF RAILWAYS (SHRI MADHAVRAO SCINDIA): (a) Number of Commission vendors engaged by Departmental Catering units are as under:—

Stations	No. of Commission Vendors
Delhi .	**132**
Allahabad	**134**
Kanmir.	
Tundla . .	156
Moradabad	120
ToTaL	